IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/699,351
Inventor(s)	:	Ronald James Jandacek *et al.*
Filed	:	October 31, 2003
Art Unit	:	1618
Examiner	:	Shirley V. Gembeh
Docket No.	:	9129L
Confirmation No.	:	2523
Customer No.	:	27752
Title	:	Compositions, Methods, and Kits Useful for the Alleviation of Gastrointestinal Effects

APPEAL BRIEF

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This Brief is filed pursuant to the appeal from the decision communicated in the Final Office Action mailed on October 13, 2010.

A timely Notice of Appeal was filed on January 6, 2011.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1, 3, 5-7, and 9-12 are finally rejected. Claims 1, 3, 5-7, and 9-12 are appealed. Claims 2, 4, 8, 13-48, and claims 54-78 are cancelled. Claims 49-53 are withdrawn. A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

STATUS OF AMENDMENTS

No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a composition comprising (page 8, line 10): (a) a stiffening agent having a complete melting point of about 33 °C or greater (page 8, line 26) which is selected from the group consisting of R-COOR', R-OR', R-CONR'R", R-NR'R", salts thereof, and mixtures thereof (page 9, lines 4-5), wherein: (i) R is selected from the group consisting of alkyl radicals having from about 14 to about 24 carbon atoms (page 9, lines 5-6), alkenyl radicals having from about 14 to about 24 carbon atoms (page 9, lines 6), alkynyl radicals having from about 14 to about 24 carbon atoms (page 9, lines 6-7), heteroalkyl radicals having from about 14 to about 24 carbon atoms (page 9, lines 7-8), heteroalkenyl radicals having from about 14 to about 24 carbon atoms (page 9, line 8), and heteroalkynyl radicals having from about 14 to about 24 carbon atoms (page 9, lines 8-9); and (ii) R' and R" are each, independently, selected from the group consisting of hydrogen, alkyl radicals, alkenyl radicals, alkynyl radicals, heteroalkyl radicals, heteroalkenyl radicals, and heteroalkynyl radicals (page 11, lines 17-18); and (b) a lipase inhibitor (page 13, lines 5-6); and (c) a non-digestible, non-absorbable, open-celled high internal phase emulsion (HIPE) foam (page 23, lines 20-22).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(I) Claims 1, 3, 5-7, and 9-12 are rejected under 35 USC § 103(a) over de Smidt et al. (US Patent No. 6,703,369) in view of Maeder et al. (US Patent No. 6,730,319) and Park (US Patent No. 5,750,585).

ARGUMENTS

THE APPLICATION OF DE SMIDT ET AL. (US PATENT NO. 6,703,369), IN VIEW OF MAEDER ET AL (US PATENT NO. 6,730,319) AND PARK (US PATENT NO. 5,750,585) DOES NOT RENDER OBVIOUS APPELLANTS' COMPOSITION

Claims 1, 3, 5-7, and 9-12 have been rejected under 35 USC §103(a) as being unpatentable over de Smidt et al. (US Patent No. 6,703,369) (hereinafter "de Smidt") in view of Maeder et al. (US Patent No. 6,730,319) (hereinafter "Maeder") and Park et al. US Patent No. 5,750,585 (hereinafter "Park"). The Office Action states that de Schmidt discloses a pharmaceutical composition comprising a glyceride ester or fatty acid, with a melting point of 37 °C, and a lipase inhibitor. The Office Action concedes that de Smidt does not teach a non-digestible, non-absorbable, open-celled HIPE foam. The Office action uses Maeder and Park to remedy this deficiency. The Office Action states that Maeder discloses a pharmaceutical composition containing a lipase inhibitor and a fatty acid having a melting point greater than or equal to 37 °C, wherein the fatty acid is selected from behenic acid. The Office Action states that Park discloses non-digestible, non-absorbable, open-celled HIPE foam compositions and methods of orally administering said foam compositions for the treatment of obesity. Appellants respectfully request reconsideration and withdrawal of the 35 USC § 103 rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some apparent reason to combine or modify reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s), when combined or modified, must teach or suggest all the claim limitations. MPEP 2143.

Neither de Smidt, Maeder, nor Park teach or suggest all of the claim limitations of independent claim 1. First de Smidt, Maeder, and Park do not teach or suggest the stiffening agent as recited in claim 1. The current application claims and discloses ethers of fatty alcohols mono-functional alcohols (R-OR'). De Smidt discloses a pharmaceutical composition comprising at least one lipase inhibitor and at least one fatty acid ester of a polyol. See column 1, lines 46-48. De Smidt discloses that a favored fatty acid ester of a polyol is a glyceride ester and the glyceride ester can be one or more monoglycerides. See column 1, line 55 and column 3, lines 63-64. However, a

monoglyceride, as disclosed in de Smidt, is an example of a polyol and a polyol is not a mono-functional alcohol. Therefore, de Smidt does not teach or suggest the stiffening agent as recited in independent claim 1. Maeder fails to remedy the deficiency of de Smidt and teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12. Additionally, Maeder does not teach a ratio of stiffening agent to lipase inhibitor, by weight, from at least 5:1.

Second, de Smidt, Maeder, and Park do not teach or suggest a non-digestible, non-absorbable, open-celled high internal phase emulsion (HIPE) foam as recited in claim 1. The Office Action concedes that de Smidt and Maeder fail to teach a non-digestible, non-absorbable, open-celled HIPE foam. Park does not remedy this deficiency. Park discloses hydrogels which are described at column 3 to column 4, starting at line 50 of column 3. However, the hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one *hydrophilic* olefin monomer compound. The hydrogels of Park are not formed from an emulsification process using hydrophobic monomers. The compositions of Park are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer. Thus, the compositions of Park and the present invention are not the same. In addition, the only mention of treatment of gastric conditions by Park is as a physical barrier due to the large swelled size of the hydrogels of Park such that the large swelled hydrogel reduces the amount of physical space in the stomach. There is nothing in Park that teaches or suggests that the hydrogels would sequester one or more lipophilic materials. Additionally, Park does not teach or suggest the stiffening agent of the current invention.

Furthermore, the present invention is directed to a composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels. See present specification page 8, lines 3-6 (emphasis added). Maeder discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form. See Column 3, lines 42-46. Appellants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. *W.L. Gore & Assocs. v. Garlock, Inc.*,

220 USPQ 303, 311 (Fed. Cir. 1983). In determining obviousness, "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and the obviousness of making the combination." *Lindeman Maschinenfabrick GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984); *Maize*, 5 USPQ 1788, 1793 (Fed. Cir. 1988). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02. One of ordinary skill in the art would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to non-liquid with the present invention. Appellants respectfully submit that if proposed modification would render the prior invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Even assuming *arguendo* that one were to combine de Smidt, Maeder, and Park one would still fall short of the Appellants' claimed invention only to arrive at a compositions that includes lipase inhibitors in combination with fatty acid esters of polyols, and a hydrogel that swells to form a physical barrier that reduces the amount of physical space in the stomach, and the composition is able to transform the active ingredient after oral ingestion from a solid to a liquid form. Therefore, the rejection has been overcome and the Appellants respectfully request withdrawal of the rejection.

SUMMARY

In view of all of the above, it is respectfully submitted that the aforementioned rejections are erroneous. The Board's reversal of the rejections is respectfully requested.

Respectfully submitted,

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CLAIMS APPENDIX

Claim 1 A composition comprising:

(a) a stiffening agent having a complete melting point of about 33 °C or greater which is selected from the group consisting of R-COOR', R-OR', R-CONR'R", R-NR'R", salts thereof, and mixtures thereof, wherein:

(i) R is selected from the group consisting of alkyl radicals having from about 14 to about 24 carbon atoms, alkenyl radicals having from about 14 to about 24 carbon atoms, alkynyl radicals having from about 14 to about 24 carbon atoms, heteroalkyl radicals having from about 14 to about 24 carbon atoms, heteroalkenyl radicals having from about 14 to about 24 carbon atoms, and heteroalkynyl radicals having from about 14 to about 24 carbon atoms; and

(ii) R' and R" are each, independently, selected from the group consisting of hydrogen, alkyl radicals, alkenyl radicals, alkynyl radicals, heteroalkyl radicals, heteroalkenyl radicals, and heteroalkynyl radicals; and

(b) a lipase inhibitor; and

(c) a non-digestible, non-absorbable, open-celled high internal phase emulsion (HIPE) foam.

Claim 3 The composition according to Claim 1, wherein the stiffening agent is selected from the group consisting of fatty acids, salts of fatty acids, and mixtures thereof.

Claim 5 The composition according to Claim 3 wherein the lipase inhibitor is selected from the group consisting of 2-amino-4H-3,1-benzoxazin-4-ones; 2-oxy-4H-3,1-benzoxazin-4-ones; 2-thio-4H-3,1-benzoxazin-4-ones; tetrahydrolipstatins; chiral alkylphosphonates; chiral isomers of beta-lactone; and mixtures thereof.

Claim 6 The composition according to Claim 5 wherein the lipase inhibitor is a compound selected from the group consisting of tetrahydrolipstatin, lipstatin, and mixtures thereof.

Claim 7 The composition according to Claim 6 comprising about 0.001% to about 15% of the lipase inhibitor and about 0.1% to about 99% of the stiffening agent, all by weight of the composition.

Claim 9 The composition according to Claim 8 comprising about_0.2% to about 95% of the stiffening agent, by weight of the composition.

Claim 10 The composition according to Claim 9 comprising about_0.8% to about 95% of the stiffening agent, by weight of the composition.

Claim 11 The composition according to Claim 10 wherein the lipase inhibitor is tetrahydrolipstatin.

Claim 12 The composition according to Claim 10 wherein the stiffening agent is selected from the group consisting of calcium stearate, behenic acid, and mixtures thereof.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None